Health Care Beat Episode 56 – AI & Health Care: Innovation, Regulation, and Reality – Part 3: AI Governance in the Hospital Setting

(This transcript was generated through AI technology.)

Amanda Genovese
Welcome to Health Care Beat, a health law podcast brought to you by Seyfarth Shaw's cross disciplinary Health Care group.

Chris DeMeo
Each Health Care Beat episode focuses on key industry trends and legal developments while identifying practical takeaways for those dealing with these issues every day.

Amanda Genovese
I'm Amanda Genovese, a Seyfarth attorney in New York.

Chris DeMeo
I'm Chris DeMeo, a Seyfarth attorney in Houston. Let's get started.
On this episode of Health Care Beat, we'll focus on the role of AI governance in the hospital setting, but first a programming note. We have our co-host back, Amanda is back. So glad to have you back in the saddle, Amanda, and good to have you virtually present.

Amanda Genovese
It's good to be back, and I'm really excited for this conversation today.

Chris DeMeo
Well, so am I, and that is because we are joined by Divya Reddy, senior director and senior corporate counsel at Houston Methodist, right here in the world famous Texas Medical Center. Divya, welcome to Health Care Beat.

Divya Reddy
Hi, thank you for having me.

Chris DeMeo
Before we get started in the weeds with the AI, can you tell us a little bit about your institution, Houston Methodist, and a little bit about your background.

Divya Reddy
Sure, of course, Houston Methodist is a huge academic medical center in the city of Houston. We support the Houston and the greater Houston area, which, for anybody who's familiar with the Houston area, stretches for miles, but we have eight hospitals and academic medical center, 36,000 employees

now and counting, and we're continuing to grow on a daily basis. And then, little bit about me, Divya Reddy, I've been with Houston Methodist now for 11 years. My area of expertise, so to speak, I started off in supply chain and IT, and about seven eight years ago, when our institution decided to give innovation importance, realized that a lot of the new innovative things were in the technology sphere, so I took that on as well, and then slowly all the new things that are coming up, they're ending up in my bucket, because it's one of my favorite things to do. So, along with innovation came the AI stuff, AI governance, and then along with that with the data governance stuff, because they tend to go hand in hand. So, anything new and cool, I get to do.

Chris DeMeo
Well, that's a good job to have. This should be a great conversation.

Divya Reddy
Yes.

Chris DeMeo
we're going to be talking about AI governance today as a large umbrella under which a lot of things can fall. Can you believe there was actually a time, a couple of years ago, when people were saying, should we adopt AI in a Health Care setting, or shouldn't we adopt AI in a Health Care setting?

Divya Reddy
I know I'd say about three years ago, or so, I was at a legal conference, and the big topic of discussion there was, should we, as you just brought up, it wasn't if it was, you know, is it too risky for Health Care organizations to take that next step, and I recall looking at, you know, colleagues from other institutions that were sitting next to me, and they were all of the same mindset, and, you know, legal - we're usually playing catch up with the most of, like, the technology folks or the clinical folks who want to push the envelope, and I recall going back to my institution and saying, "Hey, I was at a legal conference, and they were talking about, should we do this, and they said, of course, we should. At their conferences, it was kind of quite the opposite, where they were telling us new technology that was coming up the pipeline, both from like an innovation standpoint and a clinical standpoint. So it was just a matter of time where we realized that we needed to draw our guardrails right then, because it, it was happening, whether the legal folks felt while we're still opining on whether we should or not.

Chris DeMeo
You were there for when the committee launched, and you've seen it grow over the past couple of years. Can you walk us through how things started and how the committee has really evolved?

Divya Reddy
Yes, of course. So, from the onset, it was my CMIO, who's our chief medical informatics officer, so he's kind of the bridge between it and our clinical folks. He's a physician, but also has that innate technical ability in the way to communicate between the two teams, because sometimes they don't - the languages don't necessarily gel well together. So he's that nexus. And then we also had our center, our director for our Center for Innovation, and he's the guy that's constantly bringing in all the new things that they see at conferences, saying, "Hey, we have this new solution that could fix this problem that we have within the institution, and a lot of it was evolving around AI stuff. So, as I mentioned shortly after I got back from that legal conference, we, the three of us, sat together and realized, you know, we needed a structure or some type of framework for introducing AI into our system in a thoughtful manner. It wasn't just going to be this new shiny object, that new shiny object, but more so like putting thought processes of how we wanted to introduce it, and then in like a measured manner too, so that we can make sure we keep our eye on the pulses as far as regulations and things were concerned, so

it started off with three of us, but we quickly learned that the three of us did not have all the knowledge necessary from an AI standpoint. So we started inviting our colleagues and friends, so we realized there was a lot of data to be ingested and to figure out how to put the governance around that, so we invited our. Privacy officer, we realized that we needed also robust security, especially with the amount of data that these engines may be ingesting. So we invited our cybersecurity officer. We also realized that the regulations were changing very, very quickly. As I mentioned, you know that first legal conference I went to, within six months, it wasn't a should we, it's how should we most institutions realize that they were going to already have to adopt, and then figuring out similarly the legislation and the regulatory landscape was changing too, like some states were adopting very robust legal frameworks, and then others were doing a hands-off approach, so we realized we wanted to institute our own best practices for the institution, not necessarily waiting for the AI specific regulations to catch up, and so we realized maybe we needed our government affairs officer in to keep us keep an eye on the pulse, not just federal and Texas legislation, but Colorado or other states that were on the forefront of developing laws and regs to govern it, so our committee of three has evolved now to include data scientists, people from our research institute, trying to think of who our newest supply chain, our newest addition, just because at HR, HR was one of the first ones too,

Chris DeMeo
And they have the best stories too, so it's always good to have an HR person.

Divya Reddy
Yes, and especially when you're adopting AI, that's like in the HR framework too. There's lots of risks associated. It just speeds up the risk, the normal risks that you might already have.

Chris DeMeo
Sure, so you obviously need a really big room for this committee. It sounds like

Divya Reddy
Luckily it's a bunch of tech folks that are very tech savvy, so we meet via Teams every so often, every six months or so. We do try to meet in person, and it is a very large room now.

Amanda Genovese
As part of those meetings, are you also bringing in vendors to preview with you different tools? What kinds of tools are most commonly being proposed or in use today?

Divya Reddy
So we actually are the function of our governance organization, or governance structure is primarily not necessarily to vet the tools, but once, like our operators or other folks on the clinical side or operation side, find a tool to go through and have them think through lines of questioning around governance structure, about whether it fits the tenets of trustworthy AI, if it's like fair, impartial, so it helps our operators think through everything they need to think through before we decide to deploy a product, so they might come with the vendor pitch to say, "Oh, this is the most fullest thing ever, and don't worry, it's safe, there's no drift, there's no error, and then our role is to actually make them think through the process to say, hey, how do they correct for error? What is the current error rate? What's the error rate as it compares to a human being doing the same thing? So have them think through each of those things, and then for us to each of us then think through from our own areas of expertise where there may be an issue or not. Like I might look at something and say, hey, that might be a DTPA issue, or that might be a regulatory issue, from whatever standpoint our cybersecurity folks might think, hey, that's a little too much data for this vendor to have, and they're not keeping it secure, that type of framework.

Amanda Genovese
that's fantastic, and I think just having those diverse perspectives, or understanding, or expertise coming together to really hash out pressure tests, that's really kind of the only way you get to either a place of peace or a place of understanding.

Divya Reddy
You're exactly right.

Amanda Genovese
So, just what kind of AI tools are most commonly in use today? That the tools that went through this process went through the debate, which one made it out the other side?

Divya Reddy
Well, I'll tell you, when we first put our governance structure together. Remember, it was driven by a clinician tech leader, so I think his understanding from the get-go was that clinical AI was coming, especially given that we're in a Health Care setting. But we also realized that, like, as we are introducing AI into the institution, we wanted to just introduce AI, like, take the people-first approach, where we wanted to bring in AI that either supported or enhanced everyone's work, so not necessarily in one particular area, but anything that an operator brought up that thought, hey, there's a gap here that we can fix by bringing on a new AI tool. So clinical was the first focus, because that's where I think that's where they were hearing from a lot of our clinical vendors and partners that that's where AI was coming from, but that was just at the onset. Now you know there's word processing, there's all sorts of stuff that there's ambient listening technology. We've used it in the supply chain arena now too, where it computes a lot faster than just having your humans do it on a, I hate to say it this way, but like a slower basis, it amplifies the speed at which you can do some of these things.

Amanda Genovese
Oh, that's fantastic. And while you're working through these again, different tools, different processes, how does FDA approval influence the evaluation of a clinical AI tool, and does. Governance differ for non-clinical AI.

Divya Reddy
so part of, as I was going through and telling you guys how we've had to add people into our AI governance committee, one of the people we've had to add in was somebody that had intimate knowledge of how the FDA works, specifically for this reason we weren't sure when we started introducing AI about how we were going to guard against, like, drift or guard against making sure that our folks internally were monitoring the AI for all of those things, or at least making sure that the vendors were monitoring for all those purposes, and when we realized that the FDA does that, at least took that weight off of us for those types of tools that were had the FDA clearance, like the either, whether it's a 510 k clearance, saying that it's same or similar to an existing tool. We know that whatever is deployed on our end is a tool that the FDA had already has already approved, and then they're also responsible for monitoring if there's any changes in the AI, so it's more of a static AI that's not necessarily being trained on our data versus like a non-FDA monitor tool, I think the onus is on us to make sure that our end users, or whomever else that's using the tools, is working with the vendors to make sure that there's not drift and making sure that the AI is still trustworthy as it was at the onset, so it's scarier, so to speak, in the sense that there might be a little bit more risk involved, especially if it's clinical AI, but it actually takes a little bit of risk off of us to have to monitor that on our own.

Amanda Genovese

I'm going to ask basically about integration of the AI tools with the folks that would actually be utilizing it as a tool again, conceptually, like so many companies are developing or engaging vendors, but then there's a second part of our people actually using it, and they know how to use it.

Divya Reddy
Absolutely, when we're implementing these tools, we actually have our physicians, our clinicians, everyone with the input on the front end, like right now, if you're talking about clinical AI, it's a tool in the tool chest, and that's what we've maintained, that everyone still has to practice medicine as a clinician, not necessarily rely on the tool itself, but we do want them to be able to incorporate it into the workflow, not spend a bunch of money and it be like a book that you're not going to take off the shelf, so we have, we include them from the onset about building workflows, integrating it in, so we know from the front end how they're going to use it, but also they have input as to, like, you know, data retention. If an AI tool gives a result, is it going to be part of the medical record? How long does it persist? Where does it go? That type of stuff. Our clinicians do have a say in it, because it does affect how they practice, and they are - I'm sure a lot of them are both twofold concerned that you know their jobs may be at risk, but also what liability exists if you're going to rely on the tool versus their own judgment, and vice versa. If you don't rely on the tool, if somebody's going to come and say, "Hey, you think you're smarter than the AI, so I get these - we get these questions all the time, but that's why we incorporate them as part of the implementation timeline timeframe, so that they get their questions heard on the front end.

Chris DeMeo
Thanks, Divya. That's great. And where are the new ideas for AI implementation and tools coming from in your organization? Is the governance committee out there figuring out what the best tools are, and then pushing those down to operations, or does it work in some other way?

Divya Reddy
Yeah, at our institution, we've always, I think, part of our motto, I guess, so to speak, is that everyone's responsibility is innovation, and in the same way, our expectation is that everyone from the ground up, they know where the gaps are, the best gaps, and how to fill those gaps versus, you know, I might go to a conference and say, ooh, this new shiny toy, it looks great, and they might sell it for a particular purpose, but then you go to your clinician and they say, well, we already have five tools that do the same thing. Nowadays, there's so many new AI tools that all operate very, very similarly, so it's, I think, going back to Amanda's question, how you are incorporating in the clinicians and the end users to actually use the tools we're buying, we have them be a part of the decision making process on the front end, and they're the ones who might bring the AI tools to our AI governance committee, and then the committee is more vetting the tool once somebody's brought it to us, so you know there's been times where we might pass it from a legal standpoint, from a privacy standpoint, but then you know when you strip down the tool and get down to what the AI is, we ask to, is this something you really need? It just looks like a shiny Chat GPT.

Chris DeMeo
Yeah, that's that was my thinking, because as the industry grows and there's more vendors out there, it's a lot of times you just see a large language model wrapped in some other packaging from the vendor, and they're treating it like it's new. How do you deal with the inundation that you may be getting from people who are always trying to push the new AI?

Divya Reddy
So the good part, I guess, for us from a governance stand. Point is, we make our folks, if they're going to submit something, we have a very robust intake form that makes them think through these things, that says, you know, how is this different than what you already have? I think it's asking them if it

improves stuff, and then it also asks, like, if it cause it creates other issues, ancillary issues, if there's new policies that are needed, so it makes them think through the AI implications, but also whether they actually need it, because I think Chris, when you and I spoke before, I was telling you about a tool I was talking to this vendor over and over again, because I couldn't wrap my hands around like getting past this confidentiality provision issues, went back and forth with them so many times, finally got on the phone with their counsel, and when I'm talking to them, finally realize there's really no AI in the tool that they're selling, as it was literally like you mentioned an LLM, a large language model, kind of paired with the pivot table, so it's anybody could have technically done that, it was they could run it through Chat GPT and then put it in a somebody that knows Excel really well could put the spreadsheet with it, but those are the types of conversations that we sometimes end up having with our requesters or end users, saying, you know, I know it looks cool, but can't you do this yourself? Some of the stuff?

Chris DeMeo
I think you mentioned earlier, the human in the in the loop on these things, what strategies and what tactics does your committee and the institution employee to make sure that there is a human in the loop.

Divya Reddy
Yes, so from the get-go, too, when we're going through our intake form, we do ask, and the human in the loop, per se, is like the person that's putting the input in, but also validating that it's the human that's ultimately going to make the final decision, like if we're talking about clinical AI, reminding our folks that, irrespective of what the AI tool tells you, it's still the onus is on you to make that final decision. You know, a lot of folks are deploying ambient listening technology, it records, but the onus is on the person to go back through and make sure that whatever is transcribed is actually what they meant to say, so it makes things, it's much faster to go back through and proofread something to then to type it out yourself, but the onus is still on them to make sure that it actually says what it needs to say, like we have a new tool, I know a lot of our, not, it's not new anymore, but a lot of clinicians, they get the same emails from people on a day to day basis, like doc, hey, prescription refill, whatever it is, so the tool itself could potentially understand the way you speak and pre-populate, maybe start an email draft for you, that's always easier too, with the pleasantries and filling in whatever, but again, the onus is on the clinician at the end of the day to go through and make sure that whatever they're, whatever that's being sent out to the patient is exactly what they intended to send out, and just as you would monitor without AI perspective, it's the same here too.

Amanda Genovese
Diya, this has been so helpful, and I mean, what I've heard you say, as in-house legal counsel dealing with AI governance, you're dealing with risk management, you're dealing with data protection, you're deciding what tool is needed or isn't needed, a lot of this stuff. There's a lot of interplay. I mean, where do you think we go from here? Do you think it continues to evolve? Do you think that there's going to be the incorporation of additional tools? Are you all in on AI?

Divya Reddy
We are all in on AI, and absolutely. I think it's changing on a daily basis, one of the things you know, the regulatory landscape changes, right? So we're not yet where we're all comfortable with even our governance structure at this point, because you know sometimes you have federal regs, and then the next day you might not, in the same way, the state of Texas too. We saw the earlier version, and then all of us said earlier version of what they're going to roll out, then there's a new version that might not be that leaves a little bit of room for interpretation, and then you know it's the back and forth, and so it's ever evolving, you know, going back to what I, where we originally started, when I said the first legal

conference, six months later it moved, I'm telling you, every six months or so, when I check in with our legal colleagues, you see how much things have changed, even in the conversations that we're having.

Amanda Genovese
Agreed, and I will say, you know, as outside counsel, we're all in on AI as well. Anything that could lead to efficiency, additional precision, or can find ways to deliver, in our case, services, in the case of your clinicians, better health care to many patients. We should all be all in. It's just figuring out how this all works together, and again, where we go from here.

Divya Reddy
Absolutely, I agree with you 100%.

Chris DeMeo
Divya, this has been great. I could do this all day. There's so many questions that follow up that I'd like to go through, but we all have day jobs, so we've got to get back to it. But thank you so much for joining us today, and sharing your insights, and your knowledge, and your experience with our listeners.

Divya Reddy
Thank you so much for having me. This was fun.

Chris DeMeo
And thank you for joining us for another edition of Seyfarth's Health Care Beat podcast, bringing you the latest developments and pressing issues in health law so you'll never miss an episode. Be sure to visit Seyfarth.com or follow us on SoundCloud or Apple podcasts. If you enjoy this episode, please share it with your friends and colleagues. We look forward to having you with us again soon.